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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,698	09/26/2006	Mathieu Boilard	701826-057830	6783

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7590 11/15/2007

EXAMINER

MACAULEY, SHERIDAN R

ART UNIT	PAPER NUMBER
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1651

MAIL DATE	DELIVERY MODE
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11/15/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,698	BOILARD ET AL.	
	Examiner	Art Unit	
	Sheridan R. MacAuley	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 and 19-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-18 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/14/2006, 4/9/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A response and amendment was received and entered on September 28, 2007.
New claims 16-24 have been added.

Election/Restrictions

1. Applicant's election of the invention of claims 13-24 and the species "heat shock proteins" in the reply filed on September 28, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement is deemed to be proper and is therefore made FINAL.
2. It is noted that, of the claims reading upon the elected invention, the claims that read upon the elected species are claims 13-18 and 22-24.
3. Claims 1-12 and 19-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and nonelected species, there being no allowable generic or linking claim.
4. Claims 13-18 and 22-24 are examined on the merits in this office action.

Claim Objections

5. Claims 16, 17 and 22 are objected to because of the following informalities. It is recommended that the claim be amended as follows: In claim 16 and 17 word "chaperon" should be replaced with "chaperone". In claim 22, the word "thating" at the end of the claim should be changed to "thawing". Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 13-18 and 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. The term "improving" in claims 13 and 16 is a relative term that renders the claim indefinite. The term "improving" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For example, it is unclear how one of ordinary skill in the art would define the "improved" maturity of a sperm cell.

9. The term "an analog... thereof" in claim 16 also renders the claim indefinite because it is unclear what type of analog applicant is intending to claim. For example, an analog of the chaperone polypeptide could be any polypeptide, any polypeptide capable of binding chaperone receptors, or a polypeptide with a specific motif possessed by the chaperone polypeptide.

10. Claims 14, 15, 17, 18 and 22-24 are indefinite insofar as they depend from claims 13 and 16.

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 13 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 13, 14 and 16-18 are drawn to a method for preserving, restoring or improving a physiological property of sperm cells comprising contacting the sperm cells with a polypeptide, capable of binding chaperone receptors, specifically a chaperone polypeptide or an analog or fragment thereof, specifically heat shock protein, more specifically HSP60. Claims 15, 23 and 24 recite that the method is performed on fresh, frozen or thawed semen, and that the sperm cells are mammalian. Claim 22 recites that the physiological property is selected from the group comprising mobility, movement characteristics, fertility, oocyte binding, oocyte fusion, viability, acrosome integrity, acrosome reaction, maturity, and resistance to cooling, freezing or thawing.

Chaperone proteins, such as HSP60, are known to occur in human seminal fluid (see Munoz et al., Human Reproduction, 1996, 11:2600-3, p. 2601, col. 2, par. 4-5). Thus, in a natural environment, sperm cells in fresh semen are contacted with the chaperone proteins. Absent any other evidence, the process of contacting sperm cells with HSP60 preserves, restores or improves other physiological properties, such as motility or maturity.

Thus, the claimed method reads on a process that occurs in nature.

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Claim Rejections - 35 USC § 102/103

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 13-18 and 22-24 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Check et al. (Archives Androl., 1991, 26:79-81, abstract only cited) when taken in view of Munoz et al. (Human Reproduction, 1996, 11:2600-3). Claims 13, 14 and 16-18 are drawn to a method for preserving, restoring or improving a physiological property of sperm cells comprising contacting the sperm cells with a polypeptide, capable of binding chaperone receptors, specifically a chaperone polypeptide or an analog or fragment thereof, specifically heat shock protein, more specifically HSP60. Claims 15, 23 and 24 recite that the method is performed on fresh, frozen or thawed semen, and that the sperm cells are mammalian. Claim 22 recites that the physiological property is selected from the group comprising mobility, movement characteristics, fertility, oocyte binding, oocyte fusion, viability, acrosome integrity, acrosome reaction, maturity, and resistance to cooling, freezing or thawing.

18. Check teaches a method of improving mobility by adding donor human seminal plasma to fresh and frozen sperm from asthenozoospermic human males (abstract). Munoz teaches that chaperone proteins, such as HSP60, occurred in 14% of the human seminal fluid tested (p. 2604, col. 2, par. 4-5). Therefore, the seminal fluid of Check would have inherently contained HSP60.

19. Alternately, since Munoz teaches that HSP60 was only found in 14% of seminal fluid, the donor fluid taught by Check may not have contained HSP60. However, by

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replicating the experiment in the course of further experimentation, it would be likely that donor fluid containing HSP60 would be used. Thus, the use of donor fluid containing HSP60 in the method of Check would have been obvious at the time of the invention.

20. A rejection under 35 USC 102/103 is proper when the prior art process seems to be identical except that the prior art is silent as to an inherent characteristic. Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/ 103 rejection is appropriate for these types of claims as well as for composition claims (MPEP 2112, section III).

21. Therefore, Check anticipates all of the limitations of the cited claims, or in the alternative, the cited claims are rendered obvious by the teachings of Check, when taken in view of Munoz.

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Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan R. MacAuley whose telephone number is (571) 270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM
/Ruth A Davis/
Primary Examiner, AU 1651